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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,327	06/28/2004	Kenichi Sato	1029650-000152	8954
21839 7590 06/05/2007 BUCHANAN, INGERSOLL & ROONEY PC POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER WIEST, PHILIP R	
			ART UNIT 3761	PAPER NUMBER
			MAIL DATE 06/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/500,327		SATO ET AL.	
	Examiner		Art Unit	
	Phil Wiest		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 March 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/28/04, 9/28/04, 3/5/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

In the response filed 3/5/07, applicant amended claim 1 and canceled claim 4. Claims 1-3, 5, and 6 are currently pending.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 1-3, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Sioufi (US 4,938,758) in view of Kwon et al (US 6,340,770)
2. With respect to Claim 1, Al-Sioufi discloses a blood bag system comprising a container 10 holding an inactivator 12 that inactivates a microorganism in the blood, a container 2 holding an anticoagulant 9, connecting tubes connected fluid-tightly to all containers, and a tube capable of introducing a neutralizing agent 12 for neutralizing said inactivator. The tube capable of holding a neutralizing agent is connected with the container 2 holding the anticoagulant 9. The container 4 is also capable of holding a neutralizing agent. See Figures 1 and 3. Al-Sioufi, however, do not disclose an inactivator comprising a platinum compound. Kwon et al. (hereafter Kwon) disclose a platinum complex capable of binding to nucleic acid of the microorganism or an aquo complex of the platinum compound (Column 1, Lines 52-55 and Column 35, Lines 13-67). Furthermore, Kwon discloses that the platinum compound is capable of inactivating a pathogenic microorganism such as DNA (Column 1, Lines 52-55). It

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would have been obvious to one skilled in the art at the time of invention to combine the blood bag system of Al-Sioufi with the platinum complex of Kwon in order to provide proper housing in which blood can react with said platinum compound.

3. With respect to Claims 2 and 3, Kwon discloses that the platinum complex of Claim 1 can be either cisplatin or carboplatin. The use of these compounds as inactivators is well known in the art of blood purification (Column 1 Lines 43-54).

Regarding Claim 3, Kwon discloses that the aquo complex of the platinum compound comprises a dihydroxo complex (Column 35, Lines 13-67). It would have been obvious at the time of invention to combine the blood bag system of Al-Sioufi with the platinum complex of Kwon in order to provide proper housing in which blood can react with said platinum compound.

4. With respect to Claim 6, Al-Sioufi further discloses a container 10 for holding the neutralizing agent comprising a tube 11 for introducing the neutralizing agent into the system.

5. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Al-Sioufi in view of Kwon, and further in view of Howell et al. (*"Intraperitoneal cisplatin with systemic thiosulfate protection"*). Al-Sioufi discloses the blood bad system of Claim 1, but does not disclose that the use of an amino acid compound or a thiosulfate neutralizer. Howell et al. (hereafter Howell) discloses a method for treating tumors comprising the use of the use of a cisplatin inactivator and sodium thiosulfate neutralizer to neutralize the cisplatin. The addition of thiosulfate to the cisplatin solution enables

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the concentration of cisplatin to be safely escalated to 270 mg/m² body surface area. Because pathogen inactivation requires higher concentration of inactivator than cancer inactivation, this would allow pathogens to be inactivated in a more effective way while keeping the patient safe. Therefore, it would have been obvious to one skilled in the art at the time of invention in order to allow the amount of cisplatin used to be increased, thereby improving the efficiency of a pathogenic or cancer inactivation.

Response to Arguments

6. Applicant's arguments with respect to claims 1-3, 5, and 6 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Claim 1, applicant argues that the platinum compounds of the instant application are used in much higher concentrations than in anticancer treatments. However, Al-Sioufi in view of Kwon discloses the use of an identical inactivator to that of the instant invention, which is therefore capable of inactivating pathogens. As quoted in the previous office action, Kwon discloses that cisplatin is fully capable of binding to DNA (Column 1, Lines 52-60). Even though cisplatin binds to cancer cells more quickly than normal cells, it still binds to normal cells, thereby acting as an antipathogenic agent. Regarding the neutralizing agent, applicant's claim 1 discloses "a tube for introducing a neutralizing agent to neutralize the inactivator." The tube, therefore, must only be capable of introducing a neutralizing agent, and a neutralizing agent need not be present.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571) 272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PRW
5/24/07

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

